

EC-CERTIFICATE

inspection

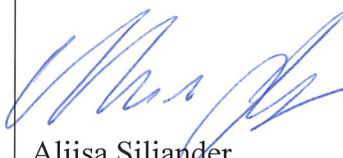
for detection and
for diagnosing
in chlamydia

final inspection of
provisions of Council
is valid until the
posed by Annex IV
specified in the

lväjä

no. 0537:
tronics Finland Oy
entie 4
FINLAND

Attachment 1 to the Certificate number: C-02-1172-794-22

Manufacturer:	Labsystems Diagnostics Oy Tiilitie 3 FI-01720 Vantaa Finland										
Activity and product category:	Design, manufacture and final inspection of reagents and reagent products for detection and quantification of toxoplasmosis. GMDN-code(s): 52441, 52440, 52436, 60897										
Products:	The certificate covers the following products: <table> <thead> <tr> <th><i>Name</i></th><th><i>Model</i></th></tr> </thead> <tbody> <tr> <td>Neonatal Toxoplasma gondii IgM FEIA</td><td>6199802</td></tr> <tr> <td>Neonatal Toxoplasma gondii IgM EIA</td><td>6199804</td></tr> <tr> <td>Toxoplasma gondii IgG EIA</td><td>6600100</td></tr> <tr> <td>Toxoplasma gondii IgG Avidity EIA</td><td>6600140</td></tr> </tbody> </table>	<i>Name</i>	<i>Model</i>	Neonatal Toxoplasma gondii IgM FEIA	6199802	Neonatal Toxoplasma gondii IgM EIA	6199804	Toxoplasma gondii IgG EIA	6600100	Toxoplasma gondii IgG Avidity EIA	6600140
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Date:	Valid from: 25 May 2022										
	   Aliisa Siljander Riikka Kylväjä										

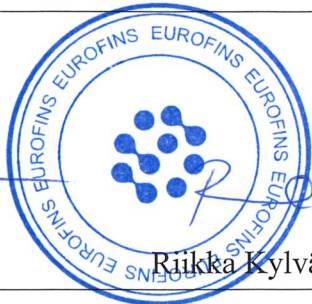
Eurofins Electric & Electronics Finland Oy is Notified Body no. 0537 under Council Directive 98/79/EC.

EUROFINS ELECTRIC & ELECTRONICS FINLAND OY

Medical Devices
Kivimiehentie 4
FI-02150 ESPOO, FINLAND

Business ID FI21741879

Attachment 2 to the Certificate number: C-02-1172-794-22

Manufacturer:	Labsystems Diagnostics Oy Tiilitie 3 FI-01720 Vantaa Finland																																		
Activity and product category:	Design, manufacture and final inspection of reagents and reagent products for diagnosing phenylketonuria. GMDN-codes: 58960,53512, 53513, 58190, 58191, 58192, 58193																																		
Products:	The certificate covers the following products: <table> <thead> <tr> <th><i>Name</i></th><th><i>Model</i></th></tr> </thead> <tbody> <tr> <td>Neonatal Phenylalanine</td><td>6199895</td></tr> <tr> <td></td><td>6199896</td></tr> <tr> <td></td><td>6199897</td></tr> <tr> <td>Neonatal Phenylalanine calibrators</td><td>6190940</td></tr> <tr> <td>Neonatal Phenylalanine controls</td><td>6190930</td></tr> <tr> <td>NeoMass AAAC</td><td>7100100</td></tr> <tr> <td>NeoMass AAAC 3.0</td><td>7100120</td></tr> <tr> <td>NeoMass AAAC Plus</td><td>7100110</td></tr> <tr> <td>NeoMass AAAC DBS Controls</td><td>710010003</td></tr> <tr> <td>NeoMass AAAC Internal Standard, Labeled Amino Acids</td><td>710010004</td></tr> <tr> <td>NeoMass AAAC Extraction Solution</td><td>710010008</td></tr> <tr> <td>NeoMass AAAC Eluent Solution</td><td>710010009</td></tr> <tr> <td>NeoMass AAAC Plus DBS Controls</td><td>710011003</td></tr> <tr> <td>NeoMass AAAC Plus Internal Standard, Labeled Amino Acids</td><td>710011004</td></tr> <tr> <td>NeoMass AAAC Plus Extraction Solution B</td><td>710011009</td></tr> <tr> <td>NeoMass AAAC Plus Eluent Solution</td><td>710011010</td></tr> </tbody> </table>	<i>Name</i>	<i>Model</i>	Neonatal Phenylalanine	6199895		6199896		6199897	Neonatal Phenylalanine calibrators	6190940	Neonatal Phenylalanine controls	6190930	NeoMass AAAC	7100100	NeoMass AAAC 3.0	7100120	NeoMass AAAC Plus	7100110	NeoMass AAAC DBS Controls	710010003	NeoMass AAAC Internal Standard, Labeled Amino Acids	710010004	NeoMass AAAC Extraction Solution	710010008	NeoMass AAAC Eluent Solution	710010009	NeoMass AAAC Plus DBS Controls	710011003	NeoMass AAAC Plus Internal Standard, Labeled Amino Acids	710011004	NeoMass AAAC Plus Extraction Solution B	710011009	NeoMass AAAC Plus Eluent Solution	710011010
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Manufacturer:	Labsystems Diagnostics Oy Tiilitie 3 FI-01720 Vantaa Finland																														
Activity and product category:	Design, manufacture and final inspection of reagents and reagent products for determining chlamydia. GMDN-codes: 50733, 50737, 50741, 50721, 50719, 50768, 50773, 50727, 58957																														
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